



DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0279]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-0279-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Department of Health and Human Services (HHS) Registration of an

Institutional Review Board Form.

Type of Collection: Reinstatement without change.

OMB No.: 0990-0279

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting reinstatement of the Office of Management and Budget (OMB) No. 0990-0279, Department of Health and Human Services (HHS) Institutional Review Board (IRB) Registration Form, with no changes, for a three-year period. That form was previously approved by OMB on February 4, 2019 and expired on February 28, 2022. The purpose of the IRB Registration Form is to provide a simplified procedure for: (1) institutions engaged in research conducted or supported by HHS to satisfy the HHS regulations for the protection of human subjects at 45 CFR 46.103(b) and 45 CFR 46.107 as promulgated in 1991 (56 FR 28012, 28022) and amended on June 23, 2005 (70 FR 36325), and 45 CFR 46, subpart E, Registration of Institutional Review Boards; and, (2) IRBs, in the United States (US), to satisfy the FDA IRB regulations at 21 CFR 56.106.

Likely Respondents: Institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS; or, in the case of FDA's requirements, each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products.

Annualized Burden Hour Table

IRB registration form	Number of respondents	Number of responses per respondent	Average burden per response	Total Burden Hours
Update and Renew Registration	5,650	2	30/60	5,650
Initial and Update Registration	350	2	45/60	525
Total				6,175

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer,

Office of the Secretary.

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